

REMARKS/ARGUMENTS

The application has been carefully reviewed in light of the December 23, 2005 Office Action. In that Office Action, claim 23 was objected to as being dependent upon a rejected base claim, but allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims. The remaining claims were rejected as either being anticipated by Biedermann et al. or the combination of Biedermann et al. with Halm et al. In response, Applicant has amended claims 1, 3, 13 and 18, canceled claims 2, 4, 14-15 and 22-23, and added new claims 24-27. In light of these amendments, and the following remarks, Applicant respectfully requests reconsideration and reexamination of the application.

DRAWINGS

The drawings were objected to for failing to include the reference number "64". Applicant submits herewith Replacement Sheet 3/3 in which the corrected figures include the reference number "64". Accordingly, Applicant believes that the objection has been overcome.

CLAIM REJECTIONS

Claims 1-5, 7-16, and 18-22 were rejected under 35 U.S.C. §102(b) as being anticipated by Biedermann et al. (U.S. Patent No. 5,961,517). Moreover, claims, 6, 17 and 20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Biedermann et al. in view of Halm et al. (U.S. Patent No. 5,738,685), based upon the assertion that Biedermann et al. disclosed the claimed invention except for a major diameter of the threaded portion being generally constant and a minor diameter of the threaded portion being tapered. Halm et al. discloses a bone screw having a major diameter of the threaded portion being generally constant, and a minor diameter of the threaded portion being tapered.

Independent claim 1 has been amended to recite that the screw assembly is a polyaxial pedicle screw assembly. The assembly comprises, as recited in claim 1, a pedicle screw having a head portion and threaded shaft portion extending therefrom. A body has an aperture adapted for receiving the threaded portion of the screw therethrough, while retaining at least a portion of the head portion in a base of the body.

The body includes a rod passageway and oppositely threaded internal and external threads. A set screw has exterior threads for engaging the internal threads of the body. A nut has internal threads for engaging the external threads of the body. The end portion of the pedicle screw includes a rounded head, wherein the head and base form a spherical joint such that body and head pivot with respect to one another.

The cited Biedermann et al. Patent discloses two embodiments, namely a monoaxial pedicle screw in Figs. 1-17, and a polyaxial pedicle screw assembly in Figs. 18-22. In the monoaxial assembly, the body and the pedicle screw are a single unit, the screw extending downwardly from an upper body portion, and thus unable to pivot with respect to the upper body portion. As described in the Background section of the present application, such monoaxial pedicle screw assemblies have many disadvantages, and thus have increasingly lost favor in the eyes of surgeons installing such spinal fixation systems.

Biedermann et al. do disclose, in column 2, lines 30-37, that the direction of the rotation of the internal screw thread and the associated locking members opposite to the direction of rotation of the outer screw thread and of the swivel nut. However, this is with respect to the monoaxial pedicle screw assembly only. There is no illustration or discussion whatsoever with respect to the second polyaxial pedicle screw assembly (illustrated in Figs. 18-22) in Biedermann et al. that the body have oppositely threaded internal and external threads such that the set screw has exterior threads for engaging the internal threads of the body and the nut has internal threads for engaging the external threads of the body so that they are tightened in opposite directions. In fact, Applicant is aware of the Biedermann et al. polyaxial pedicle screw assembly in the marketplace and in fact the locking member or set screw and the outer nut are rotated in the same direction.

As described in the Specification, the ability to simultaneously tighten the set screw and nut by rotating them in opposite directions, and thus counteracting the forces applied thereto, is of great benefit in a polyaxial pedicle screw assembly.

For a prior art reference to anticipate in terms of 35 U.S.C. §102, every element of the claimed invention must be identically shown in a single reference. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). There must be no difference between the

claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 1001, 18 USPQ2d 1896 (Fed. Cir. 1991).

Biedermann et al. do not disclose or teach a polyaxial pedicle screw assembly, as recited in independent claim 1, and Applicant respectfully asserts that a person of ordinary skill in the field of the invention would view significant differences between Applicant's polyaxial pedicle screw assembly and that of Biedermann et al. Accordingly, Applicant respectfully asserts that amended independent claim 1 is not anticipated by Biedermann et al.

Claim 3 has been amended to recite that the compression washer defines a concave facet on a lower surface thereof facing the rounded head of the pedicle screw, and a generally planar surface on a generally opposite upper surface thereof facing a rod of the assembly. Biedermann et al., as illustrated in Fig. 20, discloses a compression washer 111 having opposite concave surfaces. The lower concave surface is for engaging the head of the pedicle screw. The upper concave surface is to engage the cylindrical rod 9 while acting as a guide for the rod 9. Applicant believes that this actually presents a drawback. This is due to the fact that the surgeon must align the rod 9 with the concave upper surface of the compression washer 111 of the multiple pedicle screw assemblies. In contrast, as recited in claims 3 and 13, the upper surface of the compression washer of the present invention is generally planar. This allows the rod to have a certain degree of free movement. Thus, the multiple polyaxial pedicle screw assemblies need not be perfectly aligned with one another and the surgeon has more play and freedom with the rod placement. This is due to the fact that the rod can freely move over the generally planar or flat surface of the compression washer in the present invention, but is restricted to the groove or concave surface in Biedermann et al. Thus, Applicant respectfully asserts that neither claims 3 nor 13 are anticipated by Biedermann et al. either.

New claims 24 and 26, depending from independent claims 1 and 13 respectively, recite that the spherical joint is configured to permit up to fifteen degrees of rotation for a central axis between the assembled body and the head of the pedicle screw. By contrast, Biedermann et al. configure the outlet opening 105 in their "body"

104 with flared edges such that the pedicle screw 102 can pivot to a much greater degree. As shown in Figs. 18-22, the pedicle screw 102 could rotate at least thirty degrees from a central axis. However, this presents drawbacks. The pedicle screws 102 are inserted into the vertebrae of a spine. While a certain degree of rotation is desirable so as to assist the surgeon in installing the fastening system, as well as to permit the vertebrae to move relative to one another, this degree of movement should be limited so that the vertebrae are not overly rotated or torqued during installation of the system. Moreover, by permitting the pedicle screw 102 to rotate to such a great degree, breakage of the pedicle screw at the shank between the rounded head portion 103 and threaded portion 102 occurs more frequently.

New claims 25 and 27 recite that the shank portion of the pedicle screw between the head and threaded portions is approximately the diameter of the constant major diameter, or the diameter of the threads. This is illustrated in the present application. This reinforcement or increased width serves to lessen the possibility of the screw 102 breaking either during installation or after the patient has had the fastening system installed for some time. As illustrated in Fig. 18-22, the Biedermann et al. shank portion between the rounded head 103 and threaded portion 102 is the same diameter as the generally constant minor diameter of the screw, and thus much more susceptible to breakage.

As mentioned above, Halm et al. was combined with Biedermann et al. in rejecting claims 6, 17 and 20. However, Halm et al. failed to disclose the recitations that Biedermann et al. fail to disclose, as discussed above. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. M.P.E.P. §2143.03 (citing *In re Royka*, 180 USPQ 580 (CCPA 1974). All words in a claim must be considered in judging the patentability of that claim against the prior art. *In re Wilson*, 165 USPQ 494, 496 (CCPA 1970) As even the combination of Biedermann et al. and Halm et al. failed to teach or suggest all the claim limitations, as discussed above, independent claims 1 and 13, and thus those claims depending therefrom, are not rendered obvious.

Independent claim 18 has been amended to incorporate the recitations of dependent claim 22 and objected to claim 23, and thus is in condition for allowance.

In light of the foregoing amendments and remarks, Applicant respectfully submits that currently pending claims 1, 3, 5-13, 16-21 and 24-27 are in condition for allowance, notice of which is hereby respectfully requested.

Respectfully submitted,

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